REMARKS

In the Office Action issued on November 30, 2006, the Examiner:

- rejected claims 1 through 4 and 13 under 35 U.S.C. §102(b) as being anticipated by Kirkman (United States Patent No. 6,071,263);
- rejected claims 8 through 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of St. Germain (United States Patent No. 5,534,007);
- rejected claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Pavcnik (United States Published Application No. 20010039450);
- rejected claim 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Levine (United States Published Application No. 20040087965); and
- rejected claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of Pavcnik (United States Published Application No. 20010039450).

The Applicants have fully considered the Office Action and cited references and submit this Reply and Amendment in response to the Examiner's rejections. Reconsideration of the application for patent is requested.

Preliminary matter - Information Disclosure Statement

As a preliminary matter, the Applicants refer the Examiner to the prior Office Action (mailed on June 6, 2006). In that action, the Examiner indicated that the Information Disclosure Statements filed by the Applicants are in compliance with 37 C.F.R. §1.97, but requested that the Applicants resubmit the non-patent literature disclosed in the March 24, 2005 Information Disclosure Statement.

In the Reply and Amendment filed on October 6, 2006 in response to the June 6 Office Action, the Applicants indicated that the reason for the need for resubmission of these documents was not clear and that they were unable to determine whether a newly filed Information Disclosure Statement that includes the same documents would require payment of a fee.

As a result, the Applicants requested further explanation for the need for resubmission and an indication of whether or not the applicable fee needs to be paid with the resubmission.

In response to the current Reply and Amendment, the Applicants respectfully request that the Examiner provide the requested information or, if resubmission of the documents is not necessary, indicate that the documents have been considered.

Rejection of Claims 1 through 4 under 35 U.S.C. §102

The Examiner rejected Claims 1 through 4 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,071,263 to Kirkman ("Kirkman"). Specifically, the Examiner indicated that Kirkman "discloses a method for delivering and deploying an expandable intraluminal device" that includes the steps recited in Claims 1 through 4 of the present application for patent.

The Applicants have herein amended independent Claim 1 to indicate that the step of "deploying said expandable intraluminal medical device from the elongate member" is conducted "after the elongate member has been spaced from a wall surface of the body vessel." Each of Claims 2 through 4 depend from Claim 1 and, therefore, also include this relationship between these two separate steps of the claimed method.

As discussed in the Reply and Amendment filed on October 6, 2006, Kirkman does not disclose the steps of "spacing a portion of the elongate member from a wall surface of the body vessel" and "deploying said expandable intraluminal medical device from the elongate member" *as separate steps*.

To qualify as an anticipatory reference under 35 U.S.C. §102, a cited reference must disclose each and every limitation of the claim(s) under review. A thorough review of Kirkman reveals a complete lack of any disclosure of a method that includes these separate steps.

Indeed, review of the only figure in Kirkman that relates to deployment of an intraluminal medical device (Figure 10A) and the accompanying discussion (c.12, line 60 through c.13, line 51) reveals that **the device and method disclosed in Kirkman is physically incapable of performing these steps separately**. The anchoring wires 156, 158, 160 are the elements that function to space the catheter tip 8 from the vessel wall. As clearly illustrated in Figure 10A, the anchor wires are connected to the interior of the stent 154. Kirkman explains: "The stent 154 is connected to the catheter tip 8 by one or more connecting wires 156, 158, 160." **Because of this structural relationship between the intraluminal medical device (the stent 154) and the means for spacing (the connecting wires 156, 158, and 160), the method and device disclosed by Kirkman must accomplish spacing and deploying steps simultaneously.** As a result, Kirkman cannot anticipate Claim 1 or dependent claims 2 through 4 because each of these claims requires that these

steps be accomplished separately.

Applicants respectfully assert that the rejection of Claims 1 through 4 is improper and request its withdrawal.

Rejection of Claim 13 under 35 U.S.C. §102

The Examiner rejected Claim 13 under 35 U.S.C. §102(b) as being anticipated by United States Patent No. 6,071,263 to Kirkman ("Kirkman"). Specifically, the Examiner indicated that Kirkman discloses a delivery system that includes each of the elements recited in Claim 13 of the present application for patent.

The Applicants have not amended Claim 13 in the current Reply and Amendment and respectfully traverse the Examiner's characterization of the Kirkman disclosure.

Claim 13 is directed to a multi-component delivery system. The claim explicitly requires "an ancillary delivery device disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations." The first lumen is defined by "an elongate member" and, therefore, the ancillary device is disposed within the "elongate member." A sheath is, in turn, "circumferentially disposed about the elongate member." An example of this structural relationship between these elements is clearly illustrated in Figures 5 and 6.

The Examiner characterized Kirkman as disclosing a delivery system with "an ancillary delivery device 9 disposed in the first lumen and having a basket formed from at least two wire members 156, 158, 160 and having expanded and collapsed configurations..." (Office Action, p. 3, bottom). Applicants respectfully assert that the Examiner has mischaracterized element 9 of Kirkman (a "tip retainer") and its structural relationship to other components.

As clearly described in the disclosure and illustrated in the Figures, element 9 is a "tip retainer" formed *on* the distal end 8 of tube 4 (see c. 6, lines 44 through 48). As such, **the tip retainer 9 is not disposed in a lumen of an elongate member which, in turn, is circumferentially disposed within a sheath, as explicitly required by Claim 13**. The structural relationship of the tip retainer 9 and the tube 4 is clearly illustrated in Figure 10A. Indeed, Figures 11 through 20, which illustrate alternative embodiments, show the same structural relationship.

Kirkman simply does not disclose the structural relationship between the elements that is required by Claim 13. The reference fails, therefore, as an anticipatory reference. Applicants respectfully assert that the rejection of Claim 13 is improper and request its withdrawal.

Rejection of Claims 8 through 11 under 35 U.S.C. §103

The Examiner rejected Claims 8 through 11 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Patent No. 5,534,007 to St. Germain *et al.* ("St. Germain"). Specifically, the Examiner indicated that Kirkman "discloses the claimed steps except for the delivery system further comprising a sheath that is circumferentially disposed about the elongate member, and wherein the step of deploying the expandable intraluminal device comprises retracting the sheath from a position about the expandable intraluminal medical device."

The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claims 8 through 11.

A *prima facie* case of obviousness requires three basic criteria. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the references. Second, there must be a reasonable expectation of success. Lastly, the references must teach or suggest all limitations of the claims. (See M.P.E.P. §2143).

The Examiner has failed to establish a *prima facie* case of obviousness at least because the cited references do not teach or suggest all limitations of the claims. Each of Claims 8 through 11 depend from Claim 1, which, as described above, has herein been amended to indicate that the step of "deploying said expandable intraluminal medical device from the elongate member" is conducted "after the elongate member has been spaced from a wall surface of the body vessel."

As detailed above, Kirkman fails to disclose these steps as separate steps. Indeed, the device disclosed in Kirkman is physically incapable of performing the steps separately.

A careful review of St. Germain reveals that it also fails to disclose the separate performance of these steps. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of any of the rejected claims.

Applicants respectfully assert that the rejection of Claims 8 through 11 is improper and request its reconsideration.

Rejection of Claim 12 under 35 U.S.C. §103

The Examiner rejected Claim 12 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 12 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 12 depends from Claim 1, which has herein been amended to indicate that the step of "deploying said expandable intraluminal medical device from the elongate member" is conducted "after the elongate member has been spaced from a wall surface of the body vessel." As detailed above, Kirkman fails to disclose these steps as separate steps. Indeed, the device disclosed in Kirkman is physically incapable of performing the steps separately.

A careful review of Pavcnik reveals that it also fails to disclose the separate performance of these steps. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of any of the rejected claims. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

The Applicants note that the Examiner relied on Pavcnik for disclosure of a prosthetic venous valve. This aspect of the disclosure is irrelevant, however, considering the defect of Kirkman and Pavcnik's lack of a cure for that defect. Accordingly, the Applicants have not herein commented on the Examiner's characterization of Pavcnik as disclosing flat wire members.

Applicants respectfully assert that the rejection of Claim 12 is improper and request its reconsideration.

Rejection of Claim 14 under 35 U.S.C. §103

The Examiner rejected Claim 14 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20040087965 to Levine ("Levine"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 14 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 14 depends from Claim 13 and, therefore, includes all limitations of that claim. As detailed above, Kirkman fails to disclose the structural relationship between the elements that is required by Claim 13. Specifically, Kirkman does not disclose "an ancillary delivery device disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations," the first lumen being defined by "an elongate member"

that, in turn, is disposed within a sheath that is "circumferentially disposed about the elongate member."

A careful review of Levine reveals that it also fails to disclose such a structural relationship. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of the rejected claim. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

The Applicants note that the Examiner relied on Levine for disclosure of flat wire members. This aspect of the disclosure is irrelevant, however, considering the defect of Kirkman and Levine's lack of a cure for that defect. Accordingly, the Applicants have not herein commented on the Examiner's characterization of Levine as disclosing flat wire members.

Applicants respectfully assert that the rejection of Claim 14 is improper and request its reconsideration.

Rejection of Claim 18 under 35 U.S.C. §103

The Examiner rejected Claim 18 under 35 U.S.C. §103(a) as being unpatentably obvious over Kirkman in view of United States Published Application No. 20010039450 to Pavcnik ("Pavcnik"). The Applicants respectfully assert that the Examiner has failed to establish a *prima facie* case of obviousness in regards to her rejection of Claim 18 at least because the cited references do not teach or suggest all limitations of the rejected claim.

Claim 18 depends from Claim 13 and, therefore, includes all limitations of that claim. As detailed above, Kirkman fails to disclose the structural relationship between the elements that is required by Claim 13. Specifically, Kirkman does not disclose "an ancillary delivery device disposed in the first lumen and having a basket formed from at least two wire members and having expanded and collapsed configurations," the first lumen being defined by "an elongate member" that, in turn, is disposed within a sheath that is "circumferentially disposed about the elongate member."

A careful review of Pavcnik reveals that it also fails to disclose such a structural relationship. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of the rejected claim. This flaw prevents the asserted combination of references from establishing a *prima facie* case of obviousness.

A careful review of Pavcnik reveals that it also fails to disclose such a structural relationship. As such, it fails to cure the defect of Kirkman and, as a result, the combination of references does not disclose each and every element of the rejected claim. This flaw prevents the asserted combination of references

from establishing a *prima facie* case of obviousness.

Applicants respectfully assert that the rejection of Claim 18 is improper and request its reconsideration.

CONCLUSION

The Applicants have fully responded to the rejections listed by the Examiner in the November 30, 2006 Office Action. Applicants respectfully assert that all pending claims define patentable subject matter and request reconsideration and issuance of an appropriate Notice of Allowability.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

/J.Matthew BUCHANAN, Reg.No.47,459/

_____

J. Matthew Buchanan
Reg. No. 47,459
DUNLAP, CODDING and ROGERS, P.C.
Customer No. 42715
P.O. Box 16370
Oklahoma City, Oklahoma 73113
Telephone:(405) 607-8600
Facsimile:(405) 607-8686
E-Mail: matt_buchanan@okpatents.com
Web Site: www.okpatents.com

Attorney for Applicants